

REMARKS

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3 1. The Office Action of July 24, 2007 is hereby acknowledged. The shortened
4 statutory period of three (3) months time period for response to this Office Action expired on
5 October 24, 2007. Concurrently with the filing of this Amendment, the Applicant has requested
6 a two-month extension of time and has paid the appropriate fee. Therefore, the deadline for
7 filing the response is December 24, 2007. This Amendment Under 37 C.F.R. § 1.111 is being
8 mailed by Express Mail, Mail Label No. EM 082880312 US, addressed to Mail Stop
9 Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on
10 December 17, 2007. Therefore, this Amendment is timely filed. In the event that the
11 Commissioner for Patents should determine that any additional extension of time is required for
12 this Amendment to be timely filed and an appropriate fee is due for that extension of time, then
13 the Commissioner for Patents is hereby authorized to charge Deposit Account Number 18-2222
14 for such appropriate fee.

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16 2. The Assignee of the '078 Application has appointed Thomas I. Rozsa and the law
17 firm of Rozsa Law Group LC to prosecute and transact all business in the Patent and Trademark
18 Office connected therewith. Enclosed is a Power of Attorney by Assignee of Entire Interest and
19 a Statement Under 37 CFR 3.73(b). If there is any fee required for filing of this Power of
20 Attorney, then the Commissioner of Patents and Trademarks is hereby authorized to charge my
21 Deposit Account No. 18-2222 for any such appropriate fee.

22
23 3. The original '078 Application had a total of 12 claims wherein 2 were
24 independent claims. The '078 Application now has a total of 8 total claims wherein 4 are
25 independent claims. Therefore, there are four less total claims and two more independent claims
26 than in the originally filed application A check for \$105.00 is enclosed for the extra claim filing
27 fee. In the event that the Commissioner for Patents should determine that any additional fee is
28 due, then the Commissioner for Patents is hereby authorized to charge Deposit Account Number

1 18-2222 for the appropriate fee.

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3 4. The Patent Examiner's detailed analysis of the '078 Application is acknowledged
4 with appreciation. In accordance with the Patent Examiner's directives, the Applicants have
5 amended the Abstract to bring it into conformity with the Patent Examiner's directives.

6
7 5. With respect to the rejection under 35 U.S.C. § 112 and 35 U.S.C. § 103, the
8 Applicants have cancelled the original 12 claims of invention and have added new claims of
9 invention 13-20 which the Applicants strongly believe are patentable over the cited references
10 for the following reasons:

11 5.1 First addressing the Examiner's questions, yes, the subject matter of the
12 various claims was commonly owned at the time and the inventions covered therein were made.

13 5.2 With respect to the citation that the Examiner has cited which is Brown et al.,
14 Publication date 2003, and Burnett, Publication date August 12, 2004, the Applicants strongly
15 believe that the new claims of invention are patentable over the cited references.

16 The Examiner has cited Brown et al. as prior art. It would appear that the principal
17 ingredient in Brown's topical medicament is copper. While the inventors believe that that
18 copper is a beneficial component of the mixture, it is not critical. Therefore, it has been deleted
19 from the claims.

20 Next, the use of methyl nicotinate as a transdermal carrier, has been well documented in
21 the literature.

22 The crux of the present invention resides in the combination of Beta Alanine and
23 Histidine which work synergistically to flood Carnosine Synthetase.

24 Carnosine Synthetase converts Beta Alanine and Histidine into Carnosine, a key
25 Hydrogen ion buffer in skeletal muscle. Additionally, exogenous histidine plus the endogenous
26 beta alanine levels are enough to effect a change in carnosine levels.

27 Similarly, exogenous beta alanine plus the endogenous histidine levels are sufficient to
28 increase endogenous carnosine levels.

1 This way both components are leading to the same invention (increased carnosine
2 levels). Both will work separately because there is most likely enough endogenous histidine or
3 beta alanine and surely always sufficient Carnosine Synthetase to make this in-situ reaction
4 catalyze.

5 However, the present invention definitely works best with both histidine and beta alanine
6 in combination when provided exogenously through a trans-dermal method as is stated in this
7 invention.

8 Carnosine prevents muscular injuries and speeds up recovery times in sports. An
9 explanation of this is that high-intensity performance causes oxidative stress in muscles which
10 results in depleted Carnosine stores. The free radicals produced through high intensity muscular
11 activity cause lipid peroxidation as well as carbonylation of proteins and phospholipids. While
12 this phenomenon is documented in skeletal muscle, we believe that it is fundamental to all cells.

13 The present invention allows local concentrations of these amino acids (Beta Alanine and
14 Histidine) to be carried transdermally in sufficiently high concentration to be pharmacologically
15 active.

16 The Examiner has sited Brown's use of soy lecithin, as source of amino acids as
17 comparable to our use of Beta Alanine and Histidine. Soy lecithin (or any other form of
18 lecithin), is a complex molecule containing few amino acid-related molecules and most
19 importantly contains no Beta Alanine or Histidine. Therefore, the use of soy lecithin cannot be
20 considered prior art.

21
22 The Burnett et al. reference is cited because of its use of alcohol as a skin penetration
23 enhancer. The use of alcohol in the present invention is not to enhance tissue penetration. but
24 rather to enhance solubility of the Beta Alanine and Histidine in the excipient. The claims have
25 been amended to more accurately reflect that fact. It is immaterial to the invention what the
26 actual excipient is (e.g., water or alcohol, hydrophilic or hydrophobic), but rather that it is in a
27 form that can allow the transdermal carrier (in this case, methyl nicotinate) to deliver Beta
28 Alanine and Histidine in sufficient concentration to effect tissue repair.

6. All claims of invention are commonly owned.

7. Therefore, for all of the above-referenced reasons, it is respectfully submitted that the present claims of invention are allowable and issuance of a notice of allowance is respectfully solicited.

Respectfully submitted,

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Signature and Date

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